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Region III
Technical Guidance Manual
Risk Assessment

Chemical Concentration Data Near The Detection Limit

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Risk assessments often inappropriately report and handle data near the limits of detection. Common errors include (1) omission of detection limits, (2) failure to define detection limits which are reported, and (3) unjustified treatment of non-detects as zero. This guidance is intended to improve the quality and consistency of handling data near the detection limit in risk assessments done in Region III. (EPA/903/8-91/001)

REPORTING DETECTION LIMITS

The practice of omitting information on detection limits from risk assessments is inappropriate, both technically and ethically, because it conceals important uncertainties about potential levels of undetected risk. For example, failure to detect TCE in drinking water at a detection limit of 50 parts per billion (PPB) does not establish acceptable levels of health risk; failure to detect TCE at 0.05 ppb does. If risk assessors neglect to consider detection limits for analytical data, they may overlook serious health threats. Furthermore, detection limits should appear both in data summary tables in the body of the risk assessment, and in tables of raw data in appendices.

In a generic sense, there are two types of analytical lower limits: detection limits and quantitation limits. The detection limit is the lowest concentration that can reliably be distinguished from zero, but is below the level which is quantifiable with acceptable precision. At the detection limit, the analyte is proven to be present, but its reported concentration is an estimate. The quantitation limit is the lowest concentration which can be not only detected, but also quantified with a specified degree of precision. At the quantitation limit, the analyte is both proven present and measured reliably. The quantitation limit is always greater than the detection limit, usually by a factor of about three.

NON-DETECTION v. ZERO CONCENTRATION

The routine assumption that site-related contaminants, if undetected, are absent from samples is often unduly optimistic. Some frequently-encountered carcinogens (e.g., vinyl chloride and tetrachloroethene in drinking water, beryllium in soil) are significant potential health risks at levels below detection limits. Risk assessors should use professional judgment, augmented by the decision path described below, to decide if hazardous contaminants should be assumed present at levels below the detection limit.

The detection limit is the lowest concentration that can reliably be distinguished from zero, but is below the level which is quantifiable with acceptable precision.

The quantitation limit is the lowest concentration which can be not only detected, but also quantified with a specified degree of precision.

EXISTING GUIDANCE

Section 5.4 of the EPA Risk Assessment Guidance for Superfund (USEPA, 1989) IA recommends that all data qualifiers should be reported in the exposure assessment, and that their implications be considered before the data are used for risk assessment. Section 6.5.1 suggests use of models when monitoring data are restricted by the limit of quantitation, and Section 5.3.1 contains guidance for re-analyzing samples and determining which data should be treated qualitatively.

EPA's Guidance for Data Useability in Risk Assessment (USEPA, 1990) Section 3.3.4, subdivides generic detection limits and quantitation limits, describing six different lower analytical limits. Section 4.2 of DURA describes a strategy for selecting appropriate analytical methods, which includes consideration of risk at the detection limit.

(1) The instrument detection limit (IDL) is three times the standard deviation of seven replicate analyses at the lowest concentration of a laboratory standard that is statistically different from a blank.

(2) The method detection limit (MDL) is three times the standard deviation of seven replicate spiked samples handled as environmental samples.

(3) The sample quantitation limit (SQL) is the method detection limit corrected for sample dilution and other sample-specific adjustments.

(4) The contract required detection limit (CRDL) is the sample quantitation limit which CLP laboratories are required to maintain for inorganic analytes.

(5) The contract required quantitation limit (CRQL) is the sample quantitation limit which CLP laboratories must maintain for organic analytes.

(6) The limit of quantitation (LOQ) is the level above which analytes may be quantified with a specific precision, often +/- 30%. This precision is usually assumed to occur at ten times the standard deviation measured for the instrument detection limit.

Even with an optimum sample and analysis plan, risk assessors still confront situations where significant risks can occur below the detection limit. Neither RAGS nor DURA presents a procedure for assessing risks from undetected, but potentially present compounds, nor do they suggest a specific reporting format for detection limits. This Region III guidance document addresses these gaps in national risk assessment guidance. It is intended to augment, not replace, national guidance.

RECOMMENDED METHODOLOGY

A. Reporting Detection Limits

Risk assessments should include analytical limits in all data tables, including summary tables. One of the following should be reported for all undetected analytes, in order of preference:

Sample Quantitation Limit
Contract Required Detection Limit (or CRQL)
Limit of Quantitation (as described in DURA)

Each data table in the risk assessment should clearly describe which limits are reported, and define them.

Risk assessments should use the format shown below for all data tables. Undetected analytes should be reported as the detection limit (i.e., either the SQL, CRDL/CRQL, or LOQ, in that order) with the code "U". Analytes detected above the detection limit, but below the quantitation limit, should be reported as an estimated concentration with the code "J".

Concentration in Sample (Code)

Compound	Sample Number 123	456	789
Trichloroethene	0.1(U)	15	0.9(J)
Vinyl Chloride	0.2(U)	0.2(U)	2.2
Tetrachloroethene	5.5	3.1(J)	0.1(U)

Non-detects are reported as the sample quantitation limit, defined as three times the standard deviation of seven replicate spiked samples handled as environmental samples, corrected for sample dilution and other sample-specific adjustments.

B. Non-Detection v. Zero Concentration

Risk assessors have the following methods to choose from, for handling data below the detection limit:

*1. **Non-detects handled as detection limits** - In this highly conservative approach, all non-detects are assigned the value of the detection limit, the largest concentration of analyte that could be present but not detected. This method always produces a mean concentration which is biased high, which is inconsistent with Region III's policy of using best science in risk assessments.*

*2. **Non-detects reported as zero** - This is the best-case approach, in which all undetected chemicals are assumed absent. This method should be used only for specific chemicals which the risk assessor has determined are not likely to be present, using the decision path below.*

*3. **Non-detects reported as half the detection limit** - This approach assumes that on the average all values between the detection limit and zero could be present, and that the average value of non-detects could be as high as half the detection limit. This method (or method four, below) should be used for chemicals which the risk assessor has determined may be present below the detection limit, using the decision path below.*

*4. **Statistical estimates of concentrations below the detection limit** - Use of statistical methods to estimate concentrations below the detection limit is technically superior to method three above, but also requires considerably more effort and expertise than the three simpler methods. Also, these statistical methods are effective only for data sets having a high proportion of detects (typically, greater than 50%). Therefore, statistical predictions of concentrations below the detection limit, as described by Gilbert (1987) and reviewed by Helsel (1990), are recommended only for compounds which significantly impact the risk assessment and for which data are adequate.*

C. Decision Path for Handling Data Near the Detection Limit (DL)

Summarizing the discussion above, method one (non-detects = DL) consistently overestimates concentrations below the detection limit, and should not be used. Risk assessors should use the following decision path to select among method two (non-detects = 0), method three (non-detects = DL/2), and method four (specialized statistics) to achieve the least biased estimate of reasonable maximum exposure.

The choice of method should be based on scientific judgment about whether: (1) the undetected substance poses a significant health risk at the detection limit, (2) the undetected substance might reasonably be present in that sample, (3) the treatment of non-detects will impact the risk estimates, and (4) the database is sufficient to support statistical analysis. The decision path below, followed by examples of appropriate selections, is recommended:

1. Is the compound present at a hazardous concentration in any site-related sample?

If no, assume non-detects are zero; if yes, continue. *(Note that if the compound is not present in any sample at a hazardous level (e.g., 10^{-6} risk or a hazard quotient of 1), it probably should be dropped from the risk assessment.)*

2. Was the sample taken down-gradient of (or, if no gradient exists, adjacent to) a detectable concentration of the chemical?

If no, assume non-detects are zero; if yes, continue.

3. Do the chemical's physical-chemical characteristics (e.g., water solubility, octanol-water partitioning, vapor pressure, Henry's law constant, biodegradability, etc.), permit it reasonably to be present in the sample? Are other site-related compounds with similar characteristics present in the sample?

If no (to both questions), assume non-detects are zero; if yes (to either question), continue.

4. Does the assumption that non-detects equal DL/2 significantly impact route-specific quantitative risk estimates?

If no, assume non-detects equal DL/2; if yes, consider using statistical methods to estimate concentrations below the detection limit for that exposure route, assuming data quality permits.

EXAMPLES

1. TCE is present in groundwater on site at 500 μg/l, a potentially hazardous concentration. Elevated TCE concentrations are measured upgradient of a residential well, but TCE is not detected in the residential well itself. Other site-related chlorinated VOCs are detected in the residential well. The detection limit for TCE was 5 μg/l (equivalent to 5×10^{-6} risk under the exposure scenario in the risk assessment).

Decision Path
Step 1 - continue
Step 2 - continue
Step 3 - continue
Step 4 - assume non-detects are DL/2. If multiple well samples are available, and TCE is detected in some, consider using specialized statistical methods.

2. Chromium is present in on-site soils at 10,000 mg/kg, a potentially hazardous concentration under direct contact exposure. Chromium is not detected in an adjacent off-site soil sample, although other site-related metals are. The detection limit for chromium in soil is 0.1 mg/kg, well below a hazardous concentration under the exposure scenario in the risk assessment.

Decision Path
Step 1 - continue
Step 2 - continue
Step 3 - continue
Step 4 - assume non-detects are DL/2; using specialized statistics is unnecessary because the risk assessment would not change appreciably.

3. PCBs are not detected in 20 on-site soil samples. There is no history of PCB disposal at the site, and PCBs were not detected in any other medium.

Decision Path
Step 1 - assume non-detects are zero.

4. Vinyl chloride, a site-related contaminant, is measured in surface water downstream of the site boundary at 10 μg/l, a hazardous concentration for a resident receptor. Five hundred meters upstream of the site, vinyl chloride is not detected at a DL of 0.1 μg/l.

Decision Path
Step 1 - continue
Step 2 - assume upgradient non-detects equal zero.

5. 2,3,7,8-TCDD is detected in an unfiltered monitoring well sample at 5 ng/l, a potentially hazardous concentration. The next downgradient well has no detectable TCDD. Pentachlorophenol, also detected in the first well, is not detected in the second.

Decision Path
Step 1 - continue
Step 2 - continue
Step 3 - assume non-detects of both TCDD and PCP equal zero because of low mobility in groundwater.

References

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Helsel, D.R. (1990). Less than obvious; statistical treatment of data below the detection limit. Environ. Sci. Technol. 24(12): 1767-1774.

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